REMARKS

Claims 1-5 are pending in this application. Claims 6-8 were previously canceled in response to the Restriction Requirement issued by the Examiner. Claim 1 has been amended. No new claims have been added.

Claims 1-5 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting in view of co-pending application numbers 10/385,597 and 10/955276. Applicants will address this ground of rejection when claims in these co-pending applications are, if fact, patented.

Claims 1-5 have been rejected under 35 U.S.C. § 103(a) as being obvious over Kovacs et al., in view of Smallwood. Applicants believe that this ground of rejection is not well founded and should be withdrawn for the following reasons.

Kovacs relates to a trimonthly oral contraceptive regimen in which estrogen and progestin are administered daily for 84 consecutive days without a hormone-free period. There is no teaching in Kovacs of a transdermal extended contraceptive regimen. Accordingly, a person skilled in the art would not derive from Kovacs any expectation of the enhanced continuation and satisfaction rates in women that result from the extended transdermal contraceptive regimen of the claimed invention. Such an expectation would not be suggested to the skilled person in this art by combining Smallwood with Kovacs, because Smallwood fails to teach or even suggest an extended transdermal contraceptive regimen. Smallwood administers contraceptive hormones transdermally for only the standard 21-day regimen followed by a hormone-free period of 7 days.

Only through the teachings of the present invention do the advantages of an extended transdermal regimen become apparent to those skilled in the art. Extended transdermal administration of contraceptive hormones results in enhanced compliance, longer median time-to-first bleed, fewer mean bleeding days through day 56, and reduced median incidence of headaches as compared to cyclic transdermal administration. With respect extended contraceptive regimens utilizing other routes of administration, comparing extended transdermal administration to published data from studies of extended oral administration indicates that transdermal delivery offers superior benefits,

not only in bleeding control (absence of vaginal bleeding that requires sanitary protection of at least one pad or tampon per day), but also in continuation and satisfaction rates. In addition, comparing extended transdermal administration to published data from studies of parenteral hormonal contraceptive delivery systems indicates that the transdermal system offers superior bleeding control to some of these systems. See the instant specification at page 20, line 26 to page 21, line 9.

The Examiner argues that applicants rely on certain features, i.e., superior benefits to distinguish the claimed invention over the prior art but that such benefits are not recited in the claims. Accordingly, claim 1 has been amended to recite the longer median time-to-first bleed, fewer mean bleeding days and reduced median incidence of headaches reported for women who were administered the claimed transdermal contraceptive regimen. Support for these amendments may be found at page 20, line 23, to page 24, line 6, the data reported in Tables 6-12 and Figs. 2-4.

In view of the foregoing applicants believe that claims 1-5 patentably distinguish over the cited art and request that a Notice of Allowance directed to these claims be issued at the earliest possible date.

The Commissioner is hereby authorized to charge any additional fees which may be required in connection with the filing of this communication, or credit any overpayment, to Account No. 100750.

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

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